K020806

MAR 2 7 2002

Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person:	Thomas F. Flynn
Address:	Bayer Diagnostics 63 North Street Medfield, MA 02052
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Date Summary Prepared:	March 8, 2002

2. Device Information

Proprietary Name:	ACS:180 & ADVIA Centaur AFP
Common Name:	AFP Immunoassay
Classification Name:	Tumor Associated Antigen Immunological Test System

3. Predicate Device Information

Name:	ACS:180 & ADVIA Centaur AFP Immunoassay
Manufacturer:	Bayer Diagnostics
510(k) Number:	ACS:180 - P930036 (reclassified to class II) ADVIA Centaur - K981592

4. Device Description

The Bayer Diagnostics ACS:180 & ADVIA Centaur AFP immunoassay is a two-site immunoassay using direct chemiluminometric technology, which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a purified polyclonal rabbit anti-AFP antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-AFP antibody covalently coupled to paramagnetic particles. A direct relationship exists between the amount of AFP present in the patient sample and the amount of relative light units (RLU's) detected by the system.

5. Statement of Intended Use

The intended use of ACS:180 & ADVIA Centaur AFP Immunoassay is for the quantitative determination of alpha-fetoprotein (AFP) in the following:

human serum, as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures, using the Bayer Diagnostics ACS:180 Automated Chemiluminescence System or the ADVIA Centaur System.

6. Summary of Technological Characteristics

The Bayer Diagnostics ACS:180 & ADVIA Centaur AFP Immunoassay is a two-site sandwich Chemiluminescence immunoassay.

7. Performance Data

Sensitivity

The ADVIA Centaur AFP Immunoassay measures AFP concentration up to 1000 ng/mL with a minimum detectable concentration of 1.3 ng/mL.

The ACS:180 Immunoassay measures AFP concentration up to 1000 ng/mL with a minimum detectable concentration of 0.19 ng/mL.

Accuracy

ADVIA Centaur:

For 498 serum samples in the range of 1.3 to 943.6 ng/mL, the correlation between the ADVIA Centaur AFP and the ACS:180 AFP is described by the equation:

ADVIA Centaur AFP = 1.05 (ACS:180 AFP) - 0.3 ng/mL

Correlation coefficient (r) = 0.99

ACS:180:

For serum samples in the range of 0 to >450 ng/mL, the relationship of the ACS:180 AFP assay to four alternate AFP methods are described by the following equations:

(N = 504) ACS:180 = 0.94(Abbott IMX) + 4.6
(N =1575) ACS:180 = 0.92(Kallestd AFP/Ob) + 6.2
(N = 183) ACS:180 = 0.97(Abbott mEIA) - 1.0
(N = 477) ACS:180 = 1.10(Kallestd AFP/Ob) + 1.0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 7 2002

Mr. Thomas F. Flynn, RAC
Director, Regulatory Affairs
Bayer Corporation
63 North Street
Medfield, Massachusetts 02052-1688

Re: k020806
Trade/Device Name: ACS:180 & ADVIA Centaur AFP Immunoassay
Regulation Number: 21 CFR § 866.6010
Regulation Name: Carcinoembryonic Antigen CEA Immunological Test System
Regulatory Class: II
Product Code: LOJ
Dated: March 8, 2002
Received: March 12, 2002

Dear Mr. Flynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020806 ~~K981592~~

Device Name: Bayer Diagnostics ACS:180 & ADVIA Centaur AFP Immunoassay

Indications for Use:

For the quantitative determination of alpha-fetoprotein (AFP) in the following:

human serum, as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures, using the Bayer Diagnostics ACS:180 Automated Chemiluminescence System or the ADVIA Centaur System.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020806